

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Oral Argument Requested

**DEFENDANTS' REPLY IN SUPPORT OF THEIR
JOINT MOTION TO EXCLUDE THE OPINIONS OF
STEPHEN HECHT, PH.D.**

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Dr. Hecht's "general causation" opinions amount to little more than smoke and mirrors. His report is riddled with liability opinions that should be excluded in their entirety at this stage of the litigation, and the few "causation" opinions that are contained therein are fatally flawed and should be excluded.

Dr. Hecht's core opinion is that exposure to NDMA and NDEA leads to an increased risk of cancer in humans, but he fails to answer a fundamental question: what type(s) of cancer is NDMA or NDEA likely to cause? Throughout this litigation, Plaintiffs have sought to define "cancer" in the broadest possible terms, ignoring all nuance, including the fact that cancer is not a monolithic, catchall disease. Although Plaintiffs have suggested that as many as thirteen (13) different categories of cancer could be caused by ingestion of affected valsartan, neither Dr. Hecht nor any of Plaintiffs' other general causation experts have done anything to establish that all of these particular cancers are legitimately at issue. This is a threshold burden that Plaintiffs must sustain to establish general causation, and Dr. Hecht's opinions lend no meaningful support.

Further, Plaintiffs' opposition brief does little to rehabilitate Dr. Hecht's poorly supported, bare bones general causation opinions. Instead, Plaintiffs gloss over Dr. Hecht's most significant weaknesses, and double-down on his unreliable methodology. Most critically, Plaintiffs are unable to explain away Dr. Hecht's failure to adequately address the dose-response relationship in the context of the

levels of NDMA and NDEA that Plaintiffs may have been exposed to from Defendants' VCDs. Likewise, Plaintiffs cannot reconcile Dr. Hecht's failure to fully account for the background exposure to nitrosamines, including endogenous exposure, that all human beings share, which is a key component to the general causation question. Further, Dr. Hecht failed to properly consider the hierarchy of evidence in the scientific literature, which renders his opinions unreliable. Accordingly, Plaintiffs cannot meet their burden to demonstrate that Dr. Hecht's opinions are admissible under Rule 702, and the Court should grant Defendants' Motion.

ARGUMENT

Plaintiffs assert that Dr. Hecht is qualified, that his opinions are the product of a reliable "weight of the evidence" methodology, and that Defendants' arguments go to the weight of Hecht's testimony rather than its admissibility. Plaintiffs are simply incorrect. Both Dr. Hecht's methodology, and his application of that methodology, suffer from fatal flaws, and his conclusions are buttressed only by his subjective belief that nitrosamines in general (and NDMA and NDEA, specifically) are carcinogenic—notwithstanding what the best scientific evidence indicates. To the extent Dr. Hecht may have attempted to evaluate the "weight of the evidence," his testimony demonstrates that he misapplied that methodology. Thus, it does not matter whether Dr. Hecht utilized a recognized methodology. Where, as here, Dr.

Hecht misapplied his chosen methodology, his liability opinions masquerading as general causation opinions are just as inadmissible as if he employed no methodology at all. *See Hoekman v. Educ. Minnesota*, 335 F.R.D. 219, 236 (D. Minn. 2020) (quoting *In re Wholesale Grocery Prod. Antitrust Litig.*, 946 F.3d 995, 1001 (8th Cir. 2019)) (“[A]ny step that renders the analysis unreliable renders the expert’s testimony inadmissible . . . [regardless of] whether the step completely changes a reliable methodology or merely misapplies that methodology.”) (alterations in original).

These criticisms are not mere fodder for cross examination, as Plaintiffs argue. Rather, they strike at the heart of admissibility under Rule 702, and the Court should preclude Dr. Hecht from offering any general causation opinions at trial. *See Modern Remodeling, Inc. v. Tripod Holdings, LLC*, 2021 WL 5234698, at *6 (D. Md. Nov. 9, 2021) (stating, “[t]o acknowledge the core unreliability of expert testimony and yet leave it to the jury as a question of weight would be to abdicate the court’s gatekeeping function.”).

I. DR. HECHT FAILED TO ESTABLISH A CAUSAL ASSOCIATION BETWEEN AFFECTED VALSARTAN AND THE CANCERS THAT PLAINTIFFS ALLEGE TO BE AT ISSUE.

More than a year ago, Plaintiffs disclosed “the following types of cancer for which Plaintiffs’ Leadership *intends to provide expert reports to proceed to the general causation Daubert hearing* in the MDL: bladder, blood, breast,

colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, pharyngeal, prostate and uterine cancers.” ([Dkt. 706](#) (emphasis added).) Yet, despite Plaintiffs’ representation that they would provide expert reports to support a causal association between NDMA/NDEA and these thirteen (13) cancers, none were proffered. Instead, Plaintiffs submitted a series of broad opinions regarding the carcinogenicity of NDMA and NDEA, but never established which cancers are truly at issue.

Dr. Hecht, like Plaintiffs’ other experts, effectively ignored Plaintiffs’ obligation to establish a causal link between the exposure to affected valsartan and each cancer plaintiffs identified as being at issue. Dr. Hecht never even analyzed the evidence as to each category of cancer, let alone demonstrated an association for all of them—and for good reason. The evidence is scant regarding the carcinogenicity of NDMA in humans, and the lack of evidence linking NDEA to human cancer is even more profound. Indeed, not one of Plaintiffs’ experts—Dr. Hecht included—can point to *a single study* that demonstrates a statistically significant causal association between NDEA and twelve (12) of the thirteen (13) cancers Plaintiffs identified. The only study on which Plaintiffs can rely for any support concerning NDEA causation is a dietary study that found a statistically significant, albeit weak, association between NDEA exposure and pancreatic cancer. At minimum, this should preclude Plaintiffs from proceeding against any Defendant in this MDL with regard to NDEA and *any alleged cancer category*, other than pancreatic.

In stark contrast, Defendants’ epidemiologist—Dr. Herman Gibb—reviewed the scientific evidence related to each of the categories of cancer identified by Plaintiffs, analyzed the data using Sir Bradford Hill’s criteria, and concluded that the evidence did not support a causal association between either NDMA or NDEA and any of the cancers identified by Plaintiffs based on the levels of impurity detected in affected valsartan, or otherwise. (Ex. A, Gibb Rep. at 2, 18-21). Neither Dr. Hecht nor any of Plaintiffs other experts have provided a basis to dispute Dr. Gibb’s conclusions, and Plaintiffs, notably, did not move to preclude Dr. Gibb’s opinions.

II. DR. HECHT EFFECTIVELY DISREGARDED THE DOSE-RESPONSE RELATIONSHIP.

At most, Dr. Hecht paid lip service to the dose-response relationship in his report and during his deposition. This did not relieve him of his obligation to perform a full dose-response analysis, which he did not do. Further, not only is Dr. Hecht’s theory that there is “no threshold” for carcinogenicity related to NDMA and NDEA contrary to both science and legal precedent, Plaintiffs have subsequently rejected it as well. As a result, the Court should exclude Dr. Hecht’s opinions.

A. Meaningful Dose-Response Analysis is Required to Answer the General Causation Question in this MDL.

The dose-response relationship is the paramount principle in toxic tort litigation. *McClain v. Metabolife Int’l*, 401 F.3d 1233, 1242 (11th Cir. 2005); *Kilpatrick v. Breg, Inc.*, 2009 WL 2058384, at *7 (S.D. Fla. June 25, 2009), *aff’d*,

613 F.3d 1329 (11th Cir. 2010) (stating, the “dose-response relationship is, in fact, the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect”) (quotations omitted). Plaintiffs cannot demonstrate otherwise, although they would have the Court believe that simply because (i) Dr. Hecht included in his report the words “dose” and “duration,” and (ii) he referenced certain levels of NDMA and NDEA found in Defendants’ VCDs, that dose and duration were part of his analysis. Plaintiffs further point to Dr. Hecht’s statement that “people who ingested the valsartan with higher contamination levels and larger doses, over longer periods of time, would likely have a more substantial increased risk as opposed to those who ingested valsartan with lower contamination levels and lower doses, and for shorter periods of use.” (Opp. at 15 (quoting Hecht Rep. at 27).) This is nothing more than a rudimentary recitation of the dose-response relationship. The fact remains that Hecht did not conclude—or even attempt to calculate—at which doses and durations VCDs would increase the risk of cancer in humans. This depth of analysis was required here.

Specifically, while Dr. Hecht provided a “range” for the NDMA and NDEA levels present in Defendants’ VCDs (*i.e.*, he noted the highest and lowest level present in each Manufacturer Defendants’ affected valsartan based on internal testing), he did not perform any calculations to determine a midpoint or mean. More

fundamentally, he made no attempt calculate the dose and duration necessary to trigger a mutagenic effect, if any:

Q: And it follows from that that you made no attempt to evaluate the specific level of NDMA from any of the manufacturers' valsartan tablets that FDA measured. You didn't consider any of those specific levels in forming the opinions we see in your report; is that correct?

A: I didn't do calculations, no.

(Hecht Dep., [Dkt. 1714-16](#), at 318:12-19). Rather, for both the highest and the lowest NDMA and NDEA levels that Dr. Hecht cited in his report, he simply concluded that they posed an unacceptable risk without performing any objective analysis of dose and response to support those conclusions.

Further, Dr. Hecht's opinions and testimony are inadmissible because in failing to perform a dose-response analysis, he did not reach his so-called conclusions through the same rigor that he would normally employ in the field. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (holding that in order for expert testimony to be admissible, the expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."). Where an expert fails to identify the particular dosage and duration that will elicit an adverse response, expert testimony is unreliable. *See, e.g., In re Lipitor (Atorvastatin Calcium) Mktg. Sales Practices & Prods. Liab. Litig.*, 2015 WL 6941132, at *1 (D.S.C. Oct. 22, 2015) (stating that "Plaintiffs must demonstrate, at general causation, that particular doses of [the drug] are capable of causing [the

disease]”); *In re Prempro Prods. Liab. Litig.*, 738 F. Supp. 2d 887, 895 (E.D. Ark. 2010) (precluding expert testimony as unreliable where expert failed to specify dose or exposure levels of estrogen necessary to cause breast cancer, but merely asserted that “estrogen is carcinogenic”) (citation omitted); *In re Accutane Products Liab.*, 511 F. Supp. 2d 1288, 1293 (M.D. Fla. 2007) (stating “[a]n expert who ignores the dose-response relationship casts suspicion on the reliability of his methodology[,]” and excluding general causation experts for failure to account for dose-response relationship and an over-reliance on animal studies); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 477 (E.D. Pa. 2014) (excluding general causation experts and cautioning that “reaching conclusions about human causation without careful consideration of the dose response is a significant methodological flaw”); *Daniels-Feasel v. Forest Pharm., Inc.*, 2021 WL 4037820, at *15 (S.D.N.Y. Sept. 3, 2021) (excluding general causation expert because her “conclusion that ‘adequate data’ exists to support a dose response relationship is only supported by favorable animal data, and her failure to reconcile data that does not support her conclusions casts doubt on the reliability of her opinion on this Bradford Hill factor.”).

Dr. Hecht freely admitted that in forming his opinions as to whether the levels of NDMA and NDEA found in Defendants’ VCDs are capable of causing harm, he

failed to evaluate the specific levels of nitrosamines—something he makes sure to do when studying tobacco-specific nitrosamines:

Q: When you’ve done research on other nitrosamines and in tobacco, like the NNN and NNK, do you ever evaluate the level of NNN or NNK in writing your papers or forming your conclusions on those studies?

A: Yes, we do.

Q: The levels are important, correct?

A: Yes, they are.

(Hecht Dep., [Dkt. 1714-16](#), at 319:16-23.) Dr. Hecht’s failure to use the same rigor that he would normally employ when conducting his own independent research is fatal to the admissibility of his opinions.

B. Plaintiffs’ Recent Assertion that a Threshold Exists Directly Contradicts Dr. Hecht’s “No Threshold” Opinion.

After Defendants filed their Motion to Exclude the Opinions of Dr. Hecht, yet another irreconcilable flaw in Dr. Hecht’s conclusions emerged. Namely, Plaintiffs have now disclaimed Dr. Hecht’s “no threshold” opinion. As a result, Dr. Hecht should be precluded from testifying at trial regarding his “no threshold” theory.

Dr. Hecht offered the following unqualified opinion regarding the presence of NDMA and NDEA in Defendants’ VCDs: “[t]he safe level is zero.” (*Id.* at 166:17.) Similarly, Dr. Hecht testified later during his deposition that he “*believes[] there is no threshold*” below which point a patient would not experience any adverse effect.

(See *id.* 369:12-23.) Plaintiffs doubled down on this assertion in their opposition brief, arguing yet again that there is no threshold for carcinogenicity. (Opp. at 16.)¹

Viewed in isolation, it would appear that Plaintiffs are standing by Dr. Hecht’s “no threshold” theory. Plaintiffs, however, have unequivocally rejected that opinion as it pertains to class certification. Specifically, according to Plaintiffs’ pleadings and motion to certify a medical monitoring class, ***thresholds do exist for NDMA and NDEA*** in the context of affected valsartan. Indeed, Plaintiffs have alleged that there is a “Lifetime Cumulative Threshold” based on dose, duration, and manufacturer of valsartan API, and Plaintiffs have attempted to define that threshold:

(A) at a dose of 320 mg, the Class Member needs to have taken a combination of three (3) months of ZHP API, OR 18 months of Hetero API, OR 54 months of Mylan and/or Aurobindo API; (B) at a dose of 160 mg, the Class Member needs to have taken a combination of six (6) months of ZHP API, OR 32 months of Hetero API, OR 108 months of Mylan and/or Aurobindo API; (C) at a dose of 80 mg, the Class Member needs to have taken a combination of 12 months of ZHP API, OR 64 months of Hetero API, OR 216 months of Mylan and/or Aurobindo API; and (D) at a dose of 40 mg, the Class Member needs to have taken a combination of 24 months of ZHP API, OR 128 months of Hetero API, OR 432 months of Mylan and/or Aurobindo API. See Dkt. No. 1709 at ¶¶ 541-42.

¹ It is beyond dispute that Dr. Hecht’s “no threshold” theory defies science and has been routinely rejected by courts. See, e.g., *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1165-66 (E.D. Wash. 2009) (internal quotation omitted) (citation omitted) (stating that the no threshold theory “flies in the face of . . . dose-response”); *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 25 (D. Mass. 1995) (stating, “[t]he linear non-threshold model cannot be falsified, nor can it be validated . . . it has been rejected by the overwhelming majority of the scientific community. It has no known or potential rate of error. It is merely an hypothesis.”).

([Dkt. 1750](#) at 8-9.)

Plaintiffs cannot have it both ways. Either there is a threshold below which exposure to NDMA and NDEA in affected valsartan would pose no risk—as Plaintiffs recently asserted in their Third Amended Medical Monitoring Class Action Complaint ([Dkt. 1709](#)) and Memorandum of Law in Support of the Medical Monitoring Plaintiffs’ Motion for Class Certification ([Dkt. 1750](#))—or there is no threshold, as Plaintiffs’ general causation experts opined. Plaintiffs are playing fast and loose by even suggesting that these diametrically opposed positions are somehow consistent. But as it relates to Dr. Hecht, his testimony that there is no threshold, which contradicts Plaintiffs’ new litigation position, will only confuse the jury and is a proper basis for exclusion. *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 109 (D. Del. 2016) (citing *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n. 2 (Fed. Cir. 2006) (stating that expert testimony is properly excluded “on the basis that the evidence could confuse the jury”). Accordingly, to the extent that Dr. Hecht’s opinions are not excluded in their entirety—and they should be—the Court should preclude Dr. Hecht from testifying at trial regarding his “no threshold” theory because it has no scientific support and directly contradicts Plaintiffs’ new position regarding thresholds.

III. DR. HECHT FAILED TO ANALYZE THE BACKGROUND RISK OF NITROSAMINE EXPOSURE.

Humans are exposed to nitrosamines every day in food, water, and the air. (*See, e.g.*, Hecht Dep., [Dkt. 1714-16](#), at 100:22-23, 173:17-18.) Likewise, humans are frequently exposed to other carcinogens in their everyday life. (*See id.* at 150:18-21; 138:25-139:2 (testifying that tobacco is a Class I carcinogen); 139:3-4 (testifying that alcohol is a Class 1 carcinogen); 139:5-7 (testifying that asbestos is a Class I carcinogen); 145:19-25 (testifying that sunlight is a Class 1 carcinogen); 146:7-23 (testifying that processed meat is a Class I carcinogen).) Similarly, nitrosamines, including NDMA and NDEA, are also formed endogenously within the human body—a fact which Dr. Hecht does not dispute. (*Id.* at 187:12-19.) Thus, there are multiple avenues for exogenous and endogenous exposure to nitrosamines, including NDMA and NDEA, and other carcinogens that are common to the entire population.

Nevertheless, Dr. Hecht did not consider the background exposure of a prospective plaintiff to nitrosamines, either exogenous or endogenous. By way of illustration, Dr. Hecht failed to cite any scientific literature or study that would suggest a modest one to seven percent increase in daily nitrosamine intake (using Mylan's mean NDEA level of 0.47 ppm) would put any prospective plaintiff at an increased risk to develop cancer. (*Id.* at 183:6-23.) In order to obfuscate Dr. Hecht's deafening silence on this point, Plaintiffs merely resort to a paint-by-the-numbers

argument that it would be unethical to subject humans to those levels of NDEA and NDMA, knowing full well that humans are exposed to greater levels of nitrosamines on a daily basis. (*See, e.g.*, Opp. at 9, 13, 29.)

With respect to Dr. Hecht's failure to consider endogenous formation of NDMA and NDEA, Plaintiffs attempt to paper over this omission by claiming that because endogenous formation cannot be easily measured, Dr. Hecht was not required to take it into account when he performed his analysis. (*See, e.g., id.* at 28.) This falls woefully short of the applicable standard. Plaintiffs have the burden of proof as to both general causation and the admissibility of Dr. Hecht's testimony. *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 524 (W.D. Pa. 2003) (plaintiff bears the burden of proving general causation); *Feit v. Great-W. Life & Annuity Ins. Co.*, 460 F. Supp. 2d 632, 640 (D.N.J. 2006) (plaintiff bears the burden of demonstrating the admissibility of expert testimony). Ignoring endogenous formation of NDMA and NDEA—and other nitrosamines which, according to Hecht, are generally carcinogenic—because it is too hard to quantify is insufficient for Plaintiffs to meet their burden.

IV. DR. HECHT IGNORED THE HIERARCHY OF EVIDENCE.

In the hierarchy of scientific evidence, human epidemiology studies involving individuals who took VCDs sit at the top of the pyramid, and are widely accepted as the best available evidence of carcinogenicity in humans. (*See Reference Manual on*

Scientific Evidence, at 555-57, 559 (3d Ed. 2011); *see also* Mot. at 17-18 (discussing the hierarchy of evidence)). Plaintiffs implicitly recognize this insofar as they argue that humans cannot be given NDMA and NDEA to evaluate carcinogenic effect. (*See, e.g.*, Opp. at 18.) Plaintiffs, however, take this argument to its extreme, arguing that because NDMA and NDEA cannot ethically be given to humans, Dr. Hecht, out of necessity, had to rely on dissimilar animal studies. To be sure, Defendants do not argue that animal studies have no role to play with respect to the general causation question in this litigation.² The problem for Dr. Hecht is that he over-relies on animal studies that involve exposures that are orders of magnitude higher than any relative exposure here, affords too much weight to occupational studies that are rife with confounders, and barely considers the human epidemiological studies that constitute the best evidence. This goes directly against Dr. Hecht's purported adherence to a "weight of the evidence" methodology.

Indeed, while Dr. Hecht is understandably eager to descend the hierarchical ladder, he largely ignores the best evidence of general causation: the Pottegård and Gomm studies. These are two recent human epidemiological cohort studies

² Defendants acknowledge that animal studies are an important source of data for toxicologists. (Britt Dep., [Dkt. 1787-2](#), at 262:5-10; Johnson Dep., [Dkt. 1796-14](#), at 265:2-4; Johnson Rep., [Dkt. 1796-11](#), at 13.) Dr. Hecht, however, is not a toxicologist (Hecht Dep., [Dkt. 1714-16](#), at 65:20), and did not even attempt the toxicological analysis necessary to properly extrapolate data from animal studies to the human population of Valsartan patients.

involving patients who took affected valsartan. Mostly notably, each study found no overall increase in cancer risk in humans. Of course, Dr. Hecht glosses over the ultimate conclusions of the Pottegård and Gomm studies because they directly contradict his *ipse dixit* belief that all nitrosamines are inherently dangerous and that there is no safe threshold for NDMA and NDEA. Specifically, Plaintiffs assert that the cohorts of non-contaminated valsartan users—the control groups—“likely included people who used contaminated valsartan[,]” somehow skewing the results. (Opp. at 26.) Plaintiffs lack even a scintilla of evidence that either control group contained a single individual who received valsartan with NDMA or NDEA.³ As such, this argument should be swiftly disregarded.

CONCLUSION

In light of the foregoing arguments, as well as those set forth in Defendants’ Memorandum of Law in Support of the Joint Motion to Exclude the Opinions of Stephen S. Hecht, Ph.D., Defendants respectfully request that the Court exclude Dr. Hecht’s opinions.

³ Notably, Plaintiffs’ concern about theoretical, uncontrolled confounders in the cohort studies does not extend to the numerous confounding factors in the occupational and dietary studies.

Dated: January 6, 2022

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 6, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Seth A. Goldberg
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